

New Guidance, Renewed Partnerships

Exploring the Alphabet Soup of Non-Traditional Agreements:

CDA, DUA, MTA, MOU, CA, TA, VSA



National Council of University Research Administrators 57th Annual Meeting

August 2-5, 2015 | Washington, DC

New Guidance, Renewed Partnerships

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What is Research Administration?

- Typically the average person thinks of:
 - Grants Awards
 - Proposal Submissions
 - Deadlines
 - Budget Preparation
 - Administrative Forms
 - Sponsored Research Agreements

Money is Great, But...

- A majority of research requires non-monetary contracts

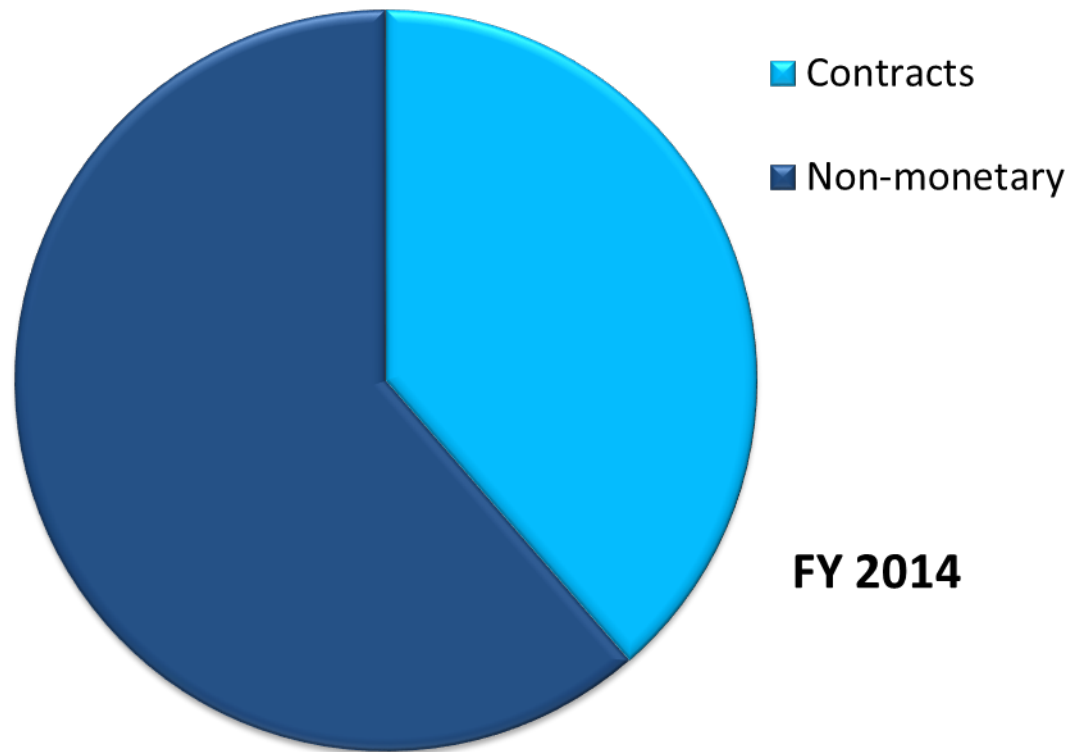
True



False



The Numbers



Non-monetary Agreements are Essential

- Facilitate sharing and licensing of research tools and software
- Protect a party's proprietary information and intellectual property
- Clearly map out each party's expectations prior to starting a project

Let's Talk About the ABC's!

Types of Non-monetary Agreements



Non-Disclosure Agreement (NDA)

Also known as:

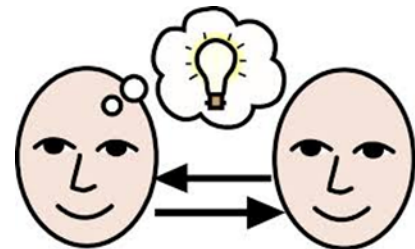
Confidentiality Agreement (CA)

Confidential Disclosure Agreement (CDA)

Proprietary Information Agreement (PIA)

Purpose

- Outlines the exchange of information a party or parties wish to keep confidential
- Parties are considering a relationship together and need to understand and evaluate the other's processes, methods, or technologies



Types of NDAs

- Mutual Disclosure
- Unilateral Disclosure
- Multi-Party Agreements

NDA Characteristics

- Typically entered into to determine whether a collaboration can occur or evaluation of possibly licensing a technology
- No Scope of Work
- No deliverables
- No money exchanged
- No generation of Intellectual Property (IP)

When is an NDA Necessary?

- An NDA should be used for discussions involving information not generally available to the public that you wish to limit how the other party uses or disseminates the information you are sharing
- For Example:
 - Writing grant proposals
 - Discussing possible collaborative projects with industry or another institution
 - Discussing licensing technologies

Why are NDAs so Important?

- NDAs are valuable to protect a party's ability to patent an invention, something that can be compromised if a public disclosure is made

Consequences of not using an NDA

- The receiving party can claim it as their own information
- The receiving party can pass it on to a third party
- The receiving party can use the information to support their own product development
- The disclosure of confidential information is considered a “public disclosure.” Because it is a public disclosure, in the public domain – this could jeopardize potential patent rights.

NDA Specifics

- Effective Date – should be before any discussions begin
- Disclosing Party – Ideally, the NDA should be mutual to prevent accidental disclosure of information not covered by the agreement
- Authorized Signatory – make sure your central office reviews the agreement and obtains the authorized signature
 - Because the institution is the party to the agreement, not the PI, only someone who has designated authority to legally bind the institution can sign

NDA Specifics

- The type of information that will be discussed needs to be clearly identified and needs to be specific.

Company and University wish to exchange certain Confidential Information pertaining to A LED device for use in ophthalmic examination and illumination. This exchange includes all communication of information between the parties in any form whatsoever, including oral, written and machine readable form, pertaining to the above subject.

NDA Specifics

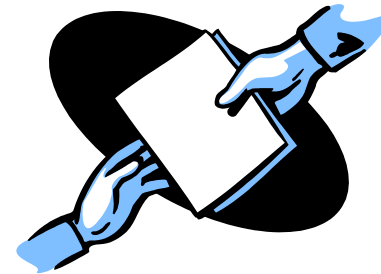
- Defined Purpose – Needs to be specific. Limits the use of confidential information disclosed.

University and Company wish to exchange the Confidential Information for the sole purpose of evaluating a potential collaboration (the “Purpose”) and each Party regards certain parts of the Confidential Information it possesses to be secret and desires to protect such Confidential Information from unauthorized disclosure or use (hereafter collectively referred to as “Confidential Information”)

NDA Specifics

- Individuals receiving party grants access to the confidential information should be limited.

Receiving Party shall restrict disclosure of the Confidential Information of the Owning Party solely to those employees of Receiving Party having a need to know such Confidential Information in order to accomplish the Purpose stated above.



NDA Specifics

- Disclosure Period – needs to be defined. 1 to 3 years ideal.

This Agreement is effective as of the Effective Date and will continue for a period of three (3) years, unless earlier terminated as provided herein. However, Receiving Party's obligations of confidentiality and restrictions on use of the Confidential Information disclosed by Owning Party, and all related remedies for breach thereof, shall survive expiration or termination of this Agreement.

NDA Specifics

- No guarantees can be made the information disclosed will match receiving party's expectations or needs.
- Parties should not be responsible for the other party's actions

NEITHER OWNING PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, WHETHER WRITTEN OR ORAL, STATUTORY, EXPRESS OR IMPLIED WITH RESPECT TO THE INFORMATION WHICH MAY BE PROVIDED HEREUNDER, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE. NEITHER OWNING PARTY SHALL BE LIABLE FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY NATURE WHATSOEVER RESULTING FROM RECEIPT OR USE OF THE INFORMATION BY THE RECEIVING PARTY.

Data Use Agreement (DUA)



Purpose

- Enables researchers to share proprietary or confidential data to perform research projects.
- Encourages collaboration and diverse thinking.
- Allows researchers to duplicate a research study's results.

DUA Characteristics

- Govern access to and treatment of data
 - Including how data is stored, maintained, and destroyed
- Protects the owning party from unauthorized disclosure of information to a third party
 - Agreement is not transferrable
- Statement of Work may be included
 - Limits receiving party's use of data

DUA Characteristics

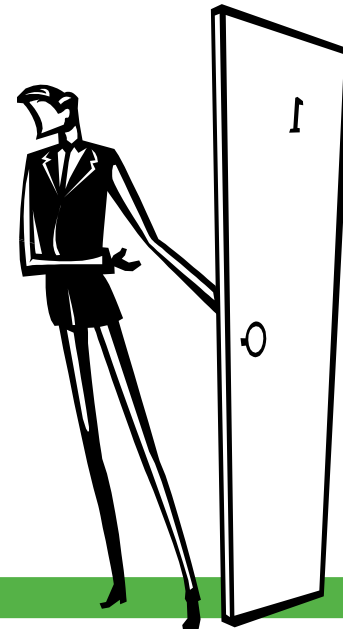
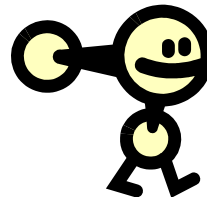
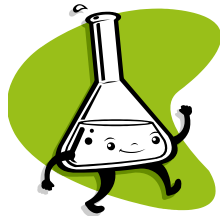
- Intellectual Property rights are addressed
 - Who owns the original data?
 - Who owns the results of the research?
- Publication should not be restricted
 - Owning party may request prior review of publications from use of data



Important to Remember

- Make sure your institution can keep the data secure and store/maintain the data as required in the Agreement. Especially important when receiving data subject to HIPAA
- Agreement should include a statement certifying the disclosing party is the owner of the data and is authorized to provide access as outlined in the Agreement.
- Important to clearly outline how data will be transferred, as well as what happens to the data once the Agreement terminates.

Materials Transfer Agreement (MTA)



MTA Purpose

A contract that governs the transfer of one or more materials from the owner or authorized licensee to an institution for research or evaluative purposes.

MTA Characteristics

- Describes ownership of the transferred material
- Plus modifications, derivatives
- Limits on use and dissemination of original material
- Purpose for use of materials
- Publication rights and confidentiality
- Rights to inventions and research results
- Materials being transferred from University may require University's Technology Transfer Office review and approval

MTA Guiding Principles

Provider

- Maintains ownership of Materials
- Should make Material available to non-profits
- Should not place restrictions on the funding sources used
- Should have no rights to inventions made by Recipient

Recipient

- Should not transfer Material to third parties
- Does not receive commercial rights to Materials
- Should not have to treat research results as confidential

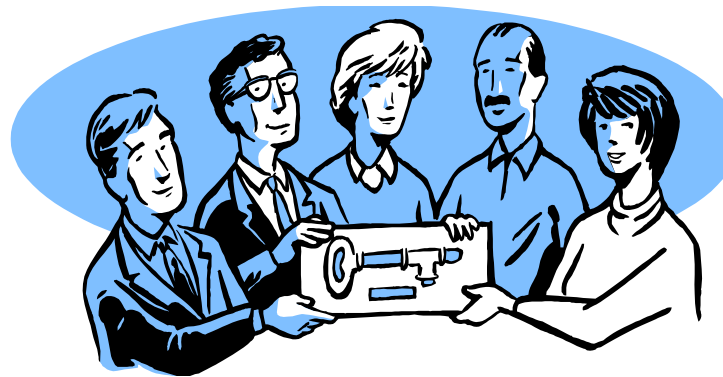
UBMTA (Uniform)Biological Material Transfer Agreement

- A master agreement that was developed by the NIH to simplify transfers of biological research materials.
- Institutions that have signed the UBMTA Master Agreement can transfer biological materials under its terms by executing an Implementing Letter for each transfer.

- See more at:

<http://www.autm.net/Content/NavigationMenu/Members/MaterialTransferAgreements/default.htm>

Membership Agreements



Purpose

- Establishes a relationship among the parties to the agreement, outlining roles and responsibilities, benefits and obligations.

Characteristics

- Outlines goals and purpose of the collaboration
- Describes benefits and obligations of membership
- Outlines terms of payment
 - May be multiple levels of membership
- Intellectual property is addressed
 - Both pre-existing and newly generated
 - Rights or no rights at all
- Clearly outlines resource management and allocation

Types of Memberships

- Federal Grant-based
 - I/UCRC
- Industry Affiliation
- Corporate/University Consortium

Membership Agreement Specifics

- Federally-sponsored membership programs have strict guidelines or provide agreement templates for establishing the terms of membership
- Consortium agreements will vary in complexity—some with a very defined governance structure
- Industry Affiliates programs support research in a general field of study and may offer access to students, facilities, and information at varying levels

Memorandum of Understanding (MOU)



MOU Characteristics

- Umbrella Agreement – basis for other types of agreements with specific scope of work and appropriate budget
- Short term – typically 3 to 5 years
- Scope is broad in nature with limited specificity – may encompass:
 - Research collaboration
 - Training
 - Faculty/student exchanges
 - Technical assistance
- Student exchange MOU may have increased specificity

Types of Entities

- US based institutions, foundations and corporations
- International institutions, corporations, and ministries of Health, Finance or Education

Common Clauses

- Purpose
- Responsibilities
- Scope of work contingent upon receipt of external funds
- Agreement to work together on applying for extramural funding

Common Clauses

- Compliance with respective institution policies
- Management of intellectual property
- Dispute Resolution
- Term and termination

International MOUs Common Clauses

- US export control laws and regulations
- Non-discrimination

MOU Characteristics

- Visa/work permits
- Licenses, authorizations and permits for employment and medical practice
- Customs duty and value added tax exemption
- Income tax exemption

Reasons for Using MOUs

- Formalizes pre-existing relationships
- Formalizes access to systems critical to project work



Important to Remember

- MOUs:
 - are not binding
 - are not enforceable
 - have no legal responsibilities or obligations
 - no joint venture, partnership is established



Inappropriate Terms

- Confidentiality
- Indemnification
- Publication restrictions
- Ownership of intellectual property
- Payment/invoicing

Teaming Agreement (TA)



When is a TA used?

- Involves 2 or more organizations (prime and subrecipients) collaborating on a proposal submission
- Usually used:
 - For complex proposals (e.g., federal contracts)
 - To define roles of multiple collaborating organizations
 - To address potential troublesome terms in advance of an award (e.g., IP)

Characteristics of a TA

- Defines roles and responsibilities for a teamed response to a funding opportunity
- Executed prior to proposal submission
- Protects confidentiality of proprietary information of each party
- Exclusivity (non-competition) clause – investigators agree not to be involved in other proposals in response to the same opportunity

Characteristics of a TA

- Sometimes includes terms (e.g., intellectual property) that will be incorporated in a future subaward
 - Consider all terms as setting a precedent for the subaward
- Terminates on execution of a subaward (if the proposal is funded) or on notice that the proposal will not be funded.
- Should also address sponsor actions that would affect the partnership
 - Examples: subrecipient's portion of project not approved by sponsor; proposal funded with large cut to budget

Visiting Scientist/Scholar Agreement (VSA)



Who would sign a VSA?

- Visitors – not employees or registered students
 - Funded by home organization (e.g. fellowship, or salary continued during sabbatical) or personal/family funds
 - Observing, interning, learning methods, etc.
- Independent access to university facilities
 - Visit is not simply a tour or speaking opportunity
 - Visitor will not always be accompanied by the host

Why is a VSA necessary?

- Intellectual property
- Confidentiality
- Health and safety
- International visitors:
 - Immigration status appropriate to proposed activities
 - Insider threats
 - Export control concerns
 - Restricted party concerns
- Institutional liability potential
- Inability to discipline

VSA highlights

- Defines scope of visitor's work, education, and/or observation
- Asserts visitor's status as a non-employee, not entitled to compensation or benefits
- Visitor agrees to be subject to institutional policies, including intellectual property policies
 - Usually host institution owns IP
- Visitor agrees to maintain confidentiality of information observed outside the visitor's work scope.

VSA highlights

- Visitor agrees to take any necessary training
- Visitor accepts liability for “injuries to people or property resulting from my acts”
- Signatures by visitor and home organization
 - Home organization acknowledges visit and intellectual property terms

Non-monetary Contracts are Cool!

- They are essential to get research done
- Facilitate research activities required by funded projects
- Without them:
 - funded projects could not be possible
 - Research Administration would not be the exciting profession it is today